CLINICAL LABS OF HAWAII

High Sensitivity Cardiac Troponin T

(cTnT GEN 5)

Effective January 30, 2019, Clinical Labs will offer in-house testing for High Sensitivity Cardiac Troponin T (cTnT GEN 5) as a replacement for current Troponin I testing.

Rapid, precise, and accurate detection of clinical, imaging, electrophysiological, and biomarker findings are the foundation for the diagnosis of acute myocardial infarction (AMI). Although current cardiac-specific assays are effective, they are often limited by decreased sensitivity and impression.

In this context, Clinical Labs of Hawaii is pleased to convert to the enhanced Generation 5 cardiac Troponin T (Roche, cTnT GEN5) for the comprehensive evaluation of AMI. The results of a comprehensive clinical-analytical validation are in line with prior large scale studies, which demonstrate a sensitivity and negative predictive value exceeding 98%. This next generation biomarker is the only FDA-approved troponin assay which meets the Universal Definition of Myocardial Infarction (UDMI) criteria for "guideline acceptable" imprecision[1] and the International Federation of Clinical Chemistry (IFCC) definition of a high sensitivity assay[2,3].

INTERPRETATION AND SPECIAL CONSIDERATIONS:	Troponin I (cTnI, Contemporary)	Generation 5 Troponin T (cTnT GEN5)
High sensitivity (IFCC)	Does not meet criteria for high sensitivity	**High sensitivity**
Total imprecision (UDMI) at the 99th percentile	CV ≥10% to ≤ 20% Clinically usable	**CV ≤10%** **Guideline acceptable**
Units	ng/mL nanograms per milliliter	**ng/L** **nanograms per LITER**
99th % upper reference limit	≤ 0.04 ng/mL (or ≤ 40 ng/L)	**<20 ng/L**
Sample	Serum and Li Heparin plasma	**Li Heparin plasma only**
Test code	TROP	**TNT5**
Clinical interpretation	As with all biomarkers, the accurate diagnosis of acute myocardial infarction requires clinical correlation and strict adherence to established practice guidelines.	

Order Code/ Test Name	Test Method	Specimen Requirement	Stability	Performed	Reported	Reference Interval	CPT Code
TNT5(3690) Troponin T GEN 5	Electro chemi-luminescent Immunoassay	1.0 mL (0.5 mL min.) Plasma Lithium Heparin (Green top)	Room Temp: 2 hours Refrigerated: 24 hours Frozen: 1 year	Sun-Sat Available Stat	Same Day	<20 ng/L[4]	84484

References

1. Universal Definition of Myocardial Infarction (UDMI) recommends using a troponin test that can measure the 99th% upper reference limit (URL) with an imprecision ≤ 10 % CV (coefficient of variation)
2. International Federation of Clinical Chemistry (IFCC) defines high sensitivity troponin as: one that can measure cTn above the LoD in ≥ 50% of healthy subjects using a troponin test that can measure the 99th% URL with an analytical imprecision ≤ 10 %
3. e601/e602
4. In accordance with current IFCC guidelines, 99th percentile value will begin to be reported as whole numbers only in ng/L units.